Rejections Under 35 U.S.C. § 112

Claims 41-49 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Within the Office Action it is specifically stated that the originally filed disclosure is silent on the use of a single wavelength. The Applicants respectfully traverse this rejection.

Within the originally filed disclosure it is specifically stated that

> the laser system of the preferred embodiment of the present invention is schematically illustrated in Figure 3. The laser generation system housing 30 includes the laser source 31 from which the laser beam 37 is provided. The laser source 31 preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35, respectively. Alternatively, any other appropriate short penetration length laser source can be used within the system of the present invention. The two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35. The galvanometer 36 then provides the laser output 37 from the laser source 31. [Specification, Page 7, lines 8-15]

A laser is by definition an optical device which generally produces light within a narrow wavelength range. Unless the laser source is a femtosecond pulsed laser source, the laser beam will by definition be a beam of light within a narrow wavelength range. A laser comprises a laser gain medium with a meta-stable excited state, and a laser cavity, to reflect light repetitively through the laser gain medium. Lasing occurs by using some means to pump electrons up into the meta-stable excited state to create a population inversion of electrons. This up pumping is then followed by stimulated relaxation from the meta-stable excited state to a lower energy state. The relaxation is driven by stimulated emission of photons as electrons in the meta-stable excited state make transitions to a lower energy state, most typically the ground state. Laser media with a multiplicity of meta-stable excited states and, therefore, a multiplicity of transitions are possible. However, except under very special conditions, one transition is typically several hundred-fold more probable than the other transitions and a medium will only lase from one transition for any given set of lasing conditions and, hence, will only produce one narrow wavelength band of laser light at one time. In order to induce one of the other less probable transitions, to produce laser light at a different wavelength, requires special manipulation of the optics within the laser cavity, special pumping of the laser medium or in some cases geometric manipulation of the laser cavity. Regardless, in the absence of extraordinary conditions, the laser

light that will be produced for any given laser medium will correspond to light produced from the most probable laser transition and the laser beam will only have one narrow emission band.

Within the instant application the applicants refer to the laser beam, which is by definition a beam of light within a narrow wavelength range. The Applicants do not refer to a stream of multi-color laser beams. Further, the applicants refer to "the laser source 31 which preferably includes two erbium lasers 32 and 34 which generate the laser beams 33 and 35." [Specification, page 7, lines 10-11] A person skilled in the art will understand that in the absence of extraordinary circumstances, the two erbium lasers will lase at very nearly the same single wavelength and that the combination of the laser beams 33 and 35 will produce the laser beam 37 or laser output at essentially the same wavelength. For at least these reasons it is requested that the rejection under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 2-5, 11-14, 17-23 and 49 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In the Office Action, it is specifically stated that in Claims 2 and 29 it is unclear what is encompassed by the term "arm feature". Further, it is stated within the Office Action that with regards to Claims 11 and 17 the term "two or more lasers which are combined in an alternating pattern" is unclear. It is further stated within the Office Action that it is unclear how the beams are combined in an alternating fashion wherein a plurality of coagulative laser pulses are generated and delivered in sequence to a target area. The Applicant respectfully traverses the rejection for the following reasons.

Within the originally filed disclosure the applicant clearly described an arm feature. Specifically the applicant states that

> the laser system of the present invention includes the articulated arm 38 to deliver the laser from the laser head 36 to the scanner handpiece 54. Within the arm 38 are a series of focussing lenses 46, 50 and 52 which are utilized to refocus the laser beam 37 as it travels through the arm 38. As is well known in the art, a laser beam traveling over a distance will converge until it reaches its focal point and then will tend to naturally expand as it travels past its focal point. The focussing lenses 46, 50 and 52 refocus the laser beam 37 so that the laser beam delivered to the scanner handpiece 54 is the same diameter as the laser beam output from the laser source 31. [Specification, Page 14, lines 13-20]

Accordingly an arm feature as recited in the Claims 2 and 29 is clearly described in the specification.

Regarding Claims 11 and 17, again attention is directed to the specification wherein it is specifically stated that "the two laser beams 33 and 35 are combined into a single laser output 37

by the galvanometer 36 which switches between the two laser outputs 33 and 35." [Specification, Page 7, lines 13-14] Thus, it is clearly described within the specification how the two laser beams 33 and 35 are used in an alternating, or equivocally a switching fashion, to form the combined output laser beam 37.

Rejections Under 35 U.S.C. § 102

Within the Office Action, Claims 1, 2, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer"). The Applicants respectfully traverse this rejection. No description to the teachings of Dwyer or detailed reasons for the rejection is given within the Office Action.

Dwyer teaches a laser device that switches between a first laser beam with a first set of laser conditions and a second laser beam with a second set of laser conditions. Dwyer teaches that by manipulating the optics within the cavity of a Nd:YAG laser, the most probable lasing transition producing laser light 1.06 microns, can effectively be shut off such that lasing can occur to produce laser light at 1.3 microns. [Dwyer, Abstract] In other words, Dwyer teaches a laser device with a tunable laser cavity for switching between two lasing conditions and thus producing two wavelengths, only one of which is generated under any one set of laser conditions.

Dwyer also teaches that a system can have two lasers with one of the lasers operating at 1.06 microns and the other laser operating at 1.3 microns, such that a surgeon can switch between the two lasers for cauterizing and cutting, respectively. However, Dwyer does not teach using one or more lasers pulsed in different ways to produce different tissue effects that are combined into a single laser beam to produce ablative and non-ablative laser pulses in a controlled fashion. In fact Dwyer does not teach combining laser beams at all.

In contrast to the teachings of Dwyer, the instant invention is directed to a laser system that is capable of operating in an ablation mode and a coagulation mode by using two or more laser sources operating at the same wavelength, which are combined in a single laser beam having a single wavelength, and wherein the pulse sequences are selectable to achieve the effects of ablating tissue or coagulating tissue. No where is this taught in the prior art.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be

treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. As discussed above, Dwyer fails to teach a medical laser with a laser source having two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Dwyer.

Claims 2 is dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Dwyer. Accordingly, Claim 2 is allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser comprising a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claim 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, Dwyer fails to teach a medical laser with a laser source with two or more lasers which are combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Dwyer.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated

without ablating any tissue. As discussed above, Dwyer fails to teach a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Dwyer.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14, 17-19 and 43-49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereinafter "Dwyer"). The Applicant respectfully traverses the rejection for the following reasons.

A prima facie case of obviousness, warranting the combination of these five (5) references has not been set forth within the Office Action. In order to combine references to support a prima facie case of obviousness, there must be some suggestion or motivation to modify a reference or combine the references, there must be a reasonable expectation of success and the references must teach all of the claimed elements. The Applicant find no suggestion within the references themselves or within the general knowledge of the art to combine such a large number of references. Further, each of the references taken singularly or in combination do not teach or suggest the combination of features taught and claimed in the instant application. (M.P.E.P. 2124).

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, 17-19 and 43-49 in the instant application. The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser." [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an

imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser." [Sklar, column 2, lines 39-43]

Sklar does not teach a laser device, or a laser system, with a laser source having two or more lasers that produce laser beams and which are alternated and combined to generate a single laser output for producing coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17. Nor does Sklar teach a laser device, or a laser system, for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Dew does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers for generating a plurality of coagulative laser pulses.

Belkin does not teach a laser or a laser system with a laser source having two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Belkin teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser system as currently claimed. Specifically, Anderson does not teach laser source with two or more lasers that produce laser beams which are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Dwyer teaches laser device which uses a means for switching the laser output between two laser wavelengths. The means for switching includes a prism which effectively bleeds the cavity from a dominant laser wavelength such that conditions for stimulated emission transitions producing laser light at 1.3 micron is achieved. [Dwyer, Abstract] In each case, the laser device is producing only one wavelength for any one set of laser conditions. Dwyer, however does not teach combining two or more lasers to generate a single laser output or laser beam as taught and claimed in the instant application.

As stated above, the current invention is a laser system that utilizes multiple lasers which produce multiple laser beams. The multiple laser beams are alternated with a galvanometer or other suitable device to produce a single laser output which generates coagulation laser pulses. The laser system preferably also is configured to generate ablation laser pulses. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser

pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson, Dwyer nor their combination.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source with two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser having a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claims 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser with a laser source with two or more lasers which are

combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pluses followed by coagulation laser pulses to the region of target tissues. The dual mode medical laser system has a laser source comprising a first laser and a second laser for generating a first laser beam and

a second laser beam at a same wavelength and a means to alternate between the first laser beam and the second laser beam to provide a single laser output to provide the ablation laser pulses and the coagulation laser pulses. The medical laser system also has a means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson, Dwyer nor their combination teach a medical laser delivery apparatus having a first and second laser that produce laser beams that are alternated to produce ablation and coagulation laser pulses from a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination.

Claims 42-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 42-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10, 20-24 and 42 have been further rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin"), the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson") and U.S. Patent No. 5,125,922 to Dwyer (hereafter "Dwyer") and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa").

Assa teaches an apparatus for delivering energy with a continuous output and can not be combined with Sklar, Dew, Belkin, Anderson or Dwyer either singularly or in combination teach the combination of features taught and claimed in the instant application. Again, the inordinate number of combined references is inconsistent with establishing a prima facie case of obviousness and there is no hint, teaching or suggestion in the prior art to combine the references in a way which would produce the invention as claimed in the instant application.

Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 4, 5, 9 and 10 are all allowable as being dependent upon an allowable base claim.

Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claims 20-24 are all allowable as being dependent upon an allowable base claim.

Claim 42 is dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson, Dwyer and their combination. Accordingly, Claim 42 is allowable as being dependent upon an allowable base claim.

For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,
HAVERSTOCK & OWENS LLP

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CERTIFICATE OF MAILING (37 CFR § 1.8(a))

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington D.C. 20231

HAVERSTOCK & OWENS LLP

Date: 11-16-01 By: Jana D. Rasco